MAY 11 2000

K000694

510(K) SUMMARY

1. SUBMITTER:

PectoFix, Inc.
481 Memorial Parkway
Metuchen, NJ 08840
Telephone: 800-776-1617

Contact: Eric Bannon, Regulatory
Date Prepared: February 18, 2000

2. DEVICE:

DSF System
Classification Name: suture, nonabsorbable, steel, monofilament
Trade Name: PectoFix DSF System

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for the PectoFix DSF System was the Ethicon USP #5 stainless steel suture, marketed by Ethicon, Inc., Somerville, NJ

4. DEVICE DESCRIPTION:

The PectoFix DSF System is a machined stainless steel plate designed for use in conjunction with stainless steel suture. The plate is deployed with the use of instrumentation onto opposing sides of the sternum. A metal spike attached to the side of the plate retains the plate in the bone. The stainless steel suture is then wrapped through and around the plate to achieve the final fixation.

5. INTENDED USE:

The intended use of the PectoFix DSF System is for the repair of the sternum following median sternotomy.

6. COMPARISON OF CHARACTERISTICS:

The PectoFix System is machined from 316L stainless steel. The plates are deployed in opposing pairs on the sternum to achieve the repair. The plate has a spike to hold the plate in place. The device is used in conjunction with stainless steel suture.

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The Ethicon stainless steel suture achieves the same end use except it is wrapped directly around the sternum.
The indications for use of the two devices are the same.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. Bench Testing: Comparison of the strength and stiffness of the PectoFix DSF System compared to the predicate device in a foam bone model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Mr. Eric Bannon
Regulatory
PectoFix, Inc.
481 Memorial Parkway
Metuchen, New Jersey 08840

Re: K000694
Trade Name: PectoFix Dynamic Sternal Fixation System (DSF)
Regulatory Class: II
Product Code: JDQ
Dated: February 23, 2000
Received: March 1, 2000

Dear Mr. Bannon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bachner

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

The intended use of the Dynamic Sternal Fixation System is for repair of the sternum following median sternotomy.

Donna R Kochman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000694